4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0079]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Animal Generic Drug User Fee Act Cover Sheet

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0632. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Form FDA 3728, Animal Generic Drug User Fee Act Cover Sheet--21 U.S.C. 379j-21 (OMB Control Number 0910-0632)--Revision

Section 741 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379j-21) establishes three different kinds of user fees: (1) Fees for certain types of abbreviated applications for generic new animal drugs, (2) annual fees for certain generic new animal drug products, and (3) annual fees for certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs (21 U.S.C. 379j-21(a)). Because concurrent submission of user fees with applications is required, the review of an application cannot begin until the fee is submitted. Form FDA 3728 is the Animal Generic Drug User Fee Act (AGDUFA) Cover Sheet, which is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees.

The Animal Generic Drug User Fee Amendments of 2013, signed by the President on June 13, 2013 (AGDUFA II) (Title II of Pub. L. 113-14), amended the FD&C Act authorizing FDA to collect user fees for certain abbreviated applications for generic new animal drugs, for certain generic new animal drug products, and for certain sponsors of such abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs. To implement changes under the reauthorization by their effective date of October 1, 2013, FDA sought and received OMB approval to update its Form FDA 3728 as described as follows:

On page 1 of the electronic questions under "Select an Application Type" users must select "Original" and then choose either, "Abbreviated New Animal Drug Application (ANADA)--under provisions of 512(b)(2) of FFDCA [the FD&C Act]" (21 U.S.C. 360b(b)(2)); or "Abbreviated New Animal Drug Application (ANADA)--for certain combination pioneer products approved under provisions of 512(d)(4) of FD&C Act." If they select the first ANADA type, they will be charge 100 percent of the application fee. If they select the second ANADA type, they will be charged at a rate of 50 percent of the original application fee. To facilitate the application process in this regard, on Form FDA 3728 we have added a line in section 3 that allows applicants to select the option, "3.2 Original Abbreviated New Animal Drug Application (ANADA)--for certain combination pioneer products approved under provisions of section 512(d)(4) of the FD&C Act."

In the Federal Register of February 18, 2014 (79 FR 9224), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden Per Response	Total Hours
3728	20	2	40	.08 (4.8 minutes)	3.2

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Respondents to this collection of information are generic animal drug applicants. Based on data for the past 3 years, FDA estimates there are approximately 20 submissions annually and a total of 3.2 burden hours.

Dated: April 17, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-09201 Filed 04/22/2014 at 8:45 am; Publication Date: 04/23/2014]